Novavax COVID-19 Vaccine

Vaccine Preparation and Administration Summary
Persons 12 Years of Age and Older

General Information

Vaccine: Novavax COVID-19 Vaccine

Multidose vial: 10 doses per vial

Dosage: 5 µg rS and 50 µg of Matrix-M™ adjuvant/0.5 mL
Do NOT dilute.

Age Indications

12 years of age and older

Vaccination Schedule

- For an up-to-date vaccination schedule for primary doses of Novavax COVID-19 Vaccine, see https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf
- Novavax is not authorized for ANY booster doses including those that received a Moderna, Novavax or Pfizer primary series.

Administration

Intramuscular (IM) injection in the deltoid muscle

Expiration Date

The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date, visit www.novavaxcovidvaccine.com, navigate to the United States Healthcare Professional section of the website, and enter the lot number printed on the carton or vial into the "Expiry Date Checker" tool.

Prepare and Administer the Vaccine

Assess recipient status:

- Screen for contraindications and precautions.
- Review vaccination history.
- Review medical considerations.

Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*

Unpunctured vials: Check the expiration date. Never use expired vaccine.

Punctured vials: Check the beyond-use-time and never use vaccine past the beyond-use time.

With the vial upright, gently swirl the vaccine. **Do NOT shake.** If the vial is shaken, contact the manufacturer. Note: Gently swirl the vaccine before withdrawing subsequent doses.

Examine the vaccine. It should be a colorless to slightly yellow, clear to mildly opalescent suspension. Do not use if liquid contains particulate matter or if it is discolored.

Using a new, sterile alcohol prep pad, cleanse the stopper of the multidose vaccine vial.

Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.

Ensure the needle and syringe are secured tightly together to prevent the vaccine from inadvertently leaking during preparation and administration.

Withdraw the correct dosage of vaccine into the syringe (0.5 mL).†
Ensure the prepared syringe is not cold to the touch.

- Discard vial when there is not enough vaccine to obtain a complete dose.
- Do NOT combine residual vaccine from multiple vials to obtain a dose.
- Regardless of the type of syringe used, ensure the amount of vaccine in the syringe is correct.

Once you can no longer withdraw a complete dose from a vaccine vial, dispose of the vial (with any remaining vaccine) as medical waste according to your local and state regulations. Contact your jurisdiction's immunization program (https://www.cdc.gov/vaccines/imz-managers/awardee-imz-websites.html) for guidance.

Note the date and time the vial was first punctured. **Keep the vaccine between 2° and 25°C (36° and 77°F) for up to 6 hours. Discard vial 6 hours after the first puncture.**

* Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

† It is not necessary to change needles between drawing vaccine from a vial and injecting it into a recipient unless the needle has been damaged or contaminated

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Prepare and Administer the Vaccine (continued)

Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.

Ensure staff has the correct PPE before administering vaccine and implement policies for the use of face coverings for vaccine recipients (if tolerated).

Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.

Observe recipients after vaccination for an immediate adverse reaction:

- **30 minutes:** Persons with a history of:
  - » A contraindication to another type of COVID-19 vaccine product
  - » Immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine
  - » Immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapies
  - » Anaphylaxis due to any cause
- **15 minutes:** All other persons

Contraindications and Precautions

Contraindications:

History of a:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the vaccine (see https://www.fda.gov/media/159897/download)

Precautions:

History of:

- Immediate allergic reaction* to any non-COVID-19 vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
- Non-severe, immediate (onset less than 4 hours after vaccination), allergic reaction to a previous dose of the COVID-19 vaccine have a precaution to the same type of COVID-19 vaccine†
- Allergy-related contraindication to one type of COVID-19 vaccine have precaution to other types of COVID-19 vaccines
- Moderate to severe acute illness, with or without fever
- History of MIS-C or MIS-A
- History of myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine

For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications.

Management of Anaphylaxis

Be prepared to manage medical emergencies.

- Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
- Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.

For more information, please see Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html.

* An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication

† People with a known allergy to polysorbate have a contraindication to both Novavax and Janssen COVID-19 vaccines and a precaution to mRNA COVID-19 vaccines. In all other cases, an allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types. Consider consultation with an allergist-immunologist to help determine if a patient with a contraindication to an Novavax can safely receive another COVID-19 vaccine. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html). Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

Document the Vaccination

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (i.e., immunization information system) for the jurisdiction as soon as practicable and no later than 72 hours after administration.

Document each recipient's vaccine administration information in the:

- **Medical record**
  - Vaccine and the date it was administered
  - Manufacturer and lot number
  - Vaccination site and route
  - Name and title of the person administering the vaccine
- **Personal vaccination record card (shot card):**
  - Date of vaccination
  - Product name/manufacturer
  - Lot number
  - Name/location of the administering clinic or healthcare professional
  - Give to the vaccine recipient.
- **Immunization information system (IIS) or "registry":**
  - Report the vaccination to the appropriate state/local IIS.

Reporting Adverse Events

Healthcare professionals are required to report to the Vaccine Adverse Event Reporting System (VAERS):

- Vaccine administration errors (whether associated with an adverse event [AE] or not)
- Serious AEs (irrespective of attribution to vaccination)
- Multisystem inflammatory syndrome (MIS) in adults or children
- Cases of COVID-19 that result in hospitalization or death
- Any additional AEs and revised safety reporting requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA

Adverse events should be reported even if the cause is uncertain. Healthcare professionals are also encouraged to report any clinically significant AEs that occur after vaccine administration. Submit reports to www.vaers.hhs.gov.

For additional information, see the vaccine manufacturer's product information at www.novavaxcovidvaccine.com.

For additional information on preventing, reporting, and managing mRNA COVID-19 vaccine administration errors, see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us-appendix.html#appendix-e.